K100333

JUN 21 2010

Section 05

510(k) Summary

1. Submitter

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2. Device name and classification

Fiab disposable High temperature battery powered cauteries:

F7244, F7233, F7234, F7277.

Code regulation name:

878.4400 - Electrosurgical cutting and coagulation device and accessories.

3. Predicates

Lawfully marketed device to which is claimed equivalence:

AARON MEDICAL INDUSTRIES high temperatures battery powered cautery, see model below.

K number	***Model***	***Description***
945492	AA01	High-temperature fine tip cautery.
945759	AA09	High-temperature loop tip with esxtended 5" shaft.

4. Device description

Self-powered devices for the cauterization of tissues and capillary vessels during surgery, without the use of a high frequency generator.

The system is started by pressing the button on the body of the cautery. The resistance of the wire of the tip, when the current passes, causes its heating guaranteeing its capacity of cauterization.
The plastic and metal materials used in the devices comply with biocompatibility requisites.
The energy produced by the continuous current is distributed as heat through a tip at a high temperature; the distribution is at short intervals of few seconds.
The cautery has the weight, size and handle suitable to allow for easy use.

5. Intended use

The device is intended for cauterization of tissues and capillary vessels during surgery, without the use of a high frequency generator.

6. Compliance to standards and performance data

Following IEC standard related to electromedical devices were used to compile present submission:

- CEI EN 60601-1 "Electromedical devices part 1: General safety standard",
- CEI EN 60601-1-2 "Electromedical devices part 1: General safety standard. Collateral standard: Electromagnetic compatibility. – Requirements and tests".

Conformity to such above standards is certified by the test report TRP_015_04 (see section 17).

Since there are no specific guidelines regulating the performances of the devices in question (Performance Standards), we have deemed sufficient to carry out the following lab tests (all results related to performance tests are included in section 18):

- Check the temperature reached by the incandescent filament is 1200°C. Temperature's measurement was made both internally (FIAB) and by a third party. Internal measurement was made with 2 methods: first using a simple encapsulated "S" thermocouple to get an indicative value of maximum temperature reached by tip and the second one using a Fiab self-built equipment to reduce inertia of temperature gauge, by this method it is possible a more accurate measurement of temperature. In order to get a confirmation of cautery ability to reach expected temperature a more accurate test was made by externally laboratory.
- Check the length of operation of the battery: from theoretical calculations we get number of activations for a fixed duration of activation. A visual operation test was made in order to verify a sufficient heating of the tip for all expected number of activations with predefined duration, being such number at least equal to 48.

Results carried out from the test showed that FIAB cauteries met the design specifications.

7. Comparison to predicate

The Fiab F72XX high temperature series cauteries have the same intended use as the predicate and do not imply new technological characteristics.

Although there are no performance standards as reported in Section 514, the cauteries are tested and produced according to all requisites laid down by the regulations in force so as to guarantee safety and effectiveness.
According to the risk-benefit analysis, the global residual risk has been deemed acceptable since it falls within the area between negligible risks and acceptable risks.
See section 12 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Fiab SpA
% Mr. Francesco Batistini
Via Costoli, 4
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Florence – Italy

JUN 21 2010

Re: K100333
Trade/Device Name: F7244, F7233, F7234, F7277 series of high temperature battery-powered cautery
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 20, 2010
Received: May 24, 2010

Dear Mr. Batistini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 04

Indications for Use

510(k) Number (if known): **K100333**

Device Name:

F7244, F7233, F7234, F7277 series of high temperature battery-powered cautery.

Indications For Use:

Cauterisation of tissues and capillary vessels during operations. No high frequency generator is required.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K100333